

REMARKS

Introduction

Claims 15-17 and 22-29 are pending, with claims 24-26 being withdrawn. Claims 18-21 have been cancelled. Claims 15, 22, and 23 have been amended. Support for these amendments can be found throughout the specification and claims, for example, in paragraph [0036], Figure 1, and Figure 2. No new matter has been added by these changes.

Rejection under 35 U.S.C. §112

The Examiner has rejected claims 22-23 under the second paragraph of 35 U.S.C. §112 as allegedly being indefinite. Applicants disagree. However, solely to expedite prosecution, claims 22 and 23 have been amended into proper Markush format as the Examiner has suggested. This rejection is now moot and its withdrawal is respectfully requested.

Rejections under 35 U.S.C. §102(b)

A. The Pradalier and Ball Documents

The Examiner has rejected claims 15-21, 23, and 27-29 under 35 U.S.C. §102(b) as allegedly being anticipated by Pradalier et al. (Pradalier), as evidenced by U.S. Patent 6,559,120 issued to Ball et al. (Ball). Applicants disagree. However, solely to expedite prosecution, the claims have been amended.

Amended claim 15 is directed to a pharmaceutical composition for sublingual, buccal or enteric administration comprising one or more peptides having a molecular weight of less than 10 kDa obtainable by hydrolysis with chymotrypsin or any other protease of an antigenic structure which induces graft rejection, allergic reaction or autoimmune disease, said antigenic structure being a protein. As the Examiner notes, Pradalier does not disclose that the grass pollen is a peptide and, further, that the peptide has a molecular weight of less than 10 kDa as the amended claims require. Thus, Pradalier cannot expressly anticipate claim 15.

The Examiner, however, cites Ball as evidence that Pradalier would inherently disclose the claimed peptides. As MPEP section 2112 sets forth, the burden rests on the Examiner to establish inherency. Importantly, "[t]he fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." See MPEP section 2112, citing *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (emphasis added). The MPEP continues stating that "[t]o establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.' Finally, the MPEP specifies that "[i]nherency, however, may not be established by probabilities or possibilities. **The mere fact that a certain thing may result from a given set of circumstances is not sufficient.**" *Id.* citing *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (emphasis added).

Pradalier, even in combination with Ball, does not disclose that the grass pollen antigens in Pradalier are always peptides having a molecular weight of less than 10 kDa as amended claim 15 requires. As discussed above, Pradalier does not disclose the claimed peptides. The passage the Examiner cites in Ball purports to show that the full amino acid sequences of grass pollens are known and does not address the claimed fragments of less than 10 kDa. Thus, neither of these documents demonstrate that the missing subject matter of claim 15 is necessarily present in the cited references, as the MPEP requires. The Examiner is improperly making an inherency rejection based on what may occur instead of what always, and thus inherently, occurs. Therefore, amended claim 15, as well as its dependent claims, are not anticipated by Pradalier, even in view of Ball, and withdrawal of the rejection under 102 is respectfully requested.

B. The McKnight Document

The Examiner has also rejected claims 15 and 22 under 35 U.S.C. §102(b) as allegedly being anticipated by U.S. Patent 6,319,679 issued to McKnight et al. (McKnight). Applicants disagree. However, solely to expedite prosecution, the claims have been amended.

As discussed previously, claim 15 now requires "one or more peptides having a molecular weight of less than 10 kDa." McKnight purports to teach compositions comprising a novel PAS kinase. This PAS kinase has 1323 amino acids. See col. 1, ll. 13-14. McKnight does not disclose the claimed peptides having a molecular weight of less than 10 kDa. Therefore, McKnight does not anticipate claim 15, or its dependent claims. Withdrawal of the rejection under 102(b) based on McKnight is respectfully requested.

Rejections under 103(a)

The Examiner has rejected claims 15-23 and 27-29 under 35 U.S.C. §103(a) as allegedly being unpatentable over Pradalier, in view of Cirkovic (Allergy 1999, 54:128-133) (Cirkovic), U.S. Patent Number 4,215,036 issued to Malley (Malley), and U.S. Patent 5,898,037 issued to Marx (Marx). Applicants disagree. However, solely to expedite prosecution, the claims have been amended.

As discussed above, amended claim 15 now requires "one or more peptides having a molecular weight of less than 10 kDa." The Examiner notes in the Office Action that Pradalier does not disclose this feature. Cirkovic purports to disclose "modified proteins [that] retain their original molecular weights, but change pi to more acidic values." See Cirkovic p. 128, results section. These modified proteins are shown in lanes b and c of figure 1 to have molecular weights of approximately 43 kDa and 67 kDa, not less than 10 kDa as the amended claims require. Thus, Cirkovic does not remedy the deficiencies of Pradalier.

Malley purports to teach modified grass pollen antigens that are made of "a flavanoid pigment, quercitin, a disaccharide, cellobiose, and a `polypeptide tail.'" See, e.g., col. 1, ll. 10-13. These compositions are not peptides having a molecular weight of less than 10 kDa and thus Malley does not teach the claimed invention. Therefore, Malley does not remedy the deficiencies of Pradalier.

The Examiner has cited Marx as allegedly rendering the claims obvious in view of Pradalier. Marx purports to teach "novel pharmaceutical compositions which comprise magnesium

compounds in hypertonic amounts." See, e.g., the Abstract. These compositions are for use in treating asthma, not for treating graft rejection, allergic reaction or autoimmune disease as the claims disclose. Marx is simply not directed to and does not teach the claimed peptides having a molecular weight of less than 10 kDa. Thus, Marx does not remedy the deficiencies of Pradalier.

For at least the above reasons, the combinations of documents cited by the Examiner do not disclose the claimed invention nor do they indicate that the claimed invention would be desirable or would be expected to successfully treat graft rejection, allergic reaction or autoimmune disease through a sublingual, buccal, or enteric form of administration. The Examiner has gleaned this information from Applicant's own disclosure and not from the prior art cited. Therefore, the rejection under 35 U.S.C. §103(a) is improper and its withdrawal is respectfully requested.

In view of the above amendments and arguments, Applicant believes the pending application is in condition for allowance.

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